[Intended use]
Quantitative measurement of lactate dehydrogenase activity in plasma or serum.
For in vitro diagnostic use only.

[Principle of the measurement]
10 µL of plasma or serum is deposited on a FUJI DRI-CHEM SLIDE LDH-PIII. After depositing, the sample spreads uniformly on the spreading layer and diffuses into the underlying coloring layer. As the process proceeds, large molecular components such as proteins or dye components are filtrated, and only small molecular components are able to permeate and diffuse into the coloring layer. The LDH catalyses the reaction of lactic acid salt with nicotinamide adenine dinucleotide (NAD+) while spreading uniformly in the spreading layer. The formed reduction type coenzyme (NADH) reduces nitrotetrazolium blue (NTB) by the catalytic reaction of diaphorase to form a diformazan dye (purple). The increase of absorbance by the generated dye is measured at 540 nm by reflective spectrophotometry and the LDH activity is calculated according to the installed formula.

Lactate + NAD+ → Pyruvic acid + NADH + H+
NTB + NADH + H+ → Diaphorase → Diformazan dye + NAD+

[Composition of the slide]
1. Multi-layered structure
2. Ingredients per slide
   - L-Lithium lactate 0.16 mg (1.7 µmol)
   - NAD+ 0.037 mg (0.055 µmol)
   - Nitrotetrazolium blue 0.12 mg (0.15 µmol)
   - Diaphorase 0.12 U

[Performance characteristics]
1. Dynamic range 50–900 U/L (0.84–15.03 µkat/L)
2. Accuracy

<table>
<thead>
<tr>
<th>Concentration range</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>50–100 U/L (0.84–1.67 µkat/L)</td>
<td>Within ± 20 U/L (Within ± 0.33 µkat/L)</td>
</tr>
<tr>
<td>100–900 U/L (1.67–15.03 µkat/L)</td>
<td>Within ± 20 %</td>
</tr>
</tbody>
</table>

3. Precision

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</tr>
</thead>
<tbody>
<tr>
<td>50–100 U/L (0.84–1.67 µkat/L)</td>
<td>SD ≤ 5 U/L (SD ≤ 0.08 µkat/L)</td>
</tr>
<tr>
<td>100–900 U/L (1.67–15.03 µkat/L)</td>
<td>CV ≤ 5 %</td>
</tr>
</tbody>
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4. Correlation
Correlation was evaluated between JSCC standard method, 37 °C and FUJI DRI-CHEM system. JSCC standard method was run on a HITACHI automated analyzer. This examination was carried out at the laboratory of FUJIFILM Corporation.

LDH...ReCCS (ERM)
Note: This reference material is applied to the reference method of FUJIFILM Corporation and is not directly applicable to FUJI DRI-CHEM SLIDE. ReCCS: Reference Material Institute for Clinical Chemistry Standards
[Symbols]

- Do not touch the center part of the slide.
- Warmed up to room temperature before opening the individual packages.
- Do not reuse
- Lot number
- Use by
- Contains sufficient for <n> tests
- Temperature limitation
- Consult instructions for use
- In vitro diagnostic medical devices
- Manufacturer
- Authorized representative in the European Community